

CLAIMS

We claim:

1 1. A pharmaceutical composition in blended or granulated form for the
2 treatment of histamine-induced disorders, comprising a therapeutically effective amount
3 of descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, and a
4 pharmaceutically acceptable inert carrier.

1 2. The pharmaceutical composition of claim 1 wherein the pharmaceutical
2 composition is substantially free of reactive excipients.

1 3. The pharmaceutical composition of claim 2 wherein the pharmaceutical
2 composition is substantially free of lactose.

1 4. The pharmaceutical composition of claim 1 wherein the therapeutically
2 effective amount of descarboethoxyloratadine is about 0.1 mg to 10 mg.

1 5. The pharmaceutical composition of claim 4 wherein the therapeutically
2 effective amount of descarboethoxyloratadine is about 0.1 mg to 5 mg.

1 6. The pharmaceutical composition of claim 1 further comprising a
2 therapeutically effective amount of an analgesic.

1 7. The pharmaceutical composition of claim 6 wherein the analgesic is
2 selected from the group consisting of acetylsalicylic acid, acetaminophen, ibuprofen,
3 ketoprofen, naproxen or a pharmaceutically acceptable salt thereof.

1 8. The pharmaceutical composition of claim 1 further comprising a
2 therapeutically effective amount of a decongestant.

1 9. The pharmaceutical composition of claim 1 wherein the composition is
2 present in one of tablet or capsule form.

1 10. The pharmaceutical composition of claim 7 wherein the composition is
2 present in tablet form.

1 11. A method of treating cough, cold, cold-like and flu symptoms and the
2 discomfort, headache, pain, fever and general malaise associated therewith, comprising
3 administering a pharmaceutical composition according to claim 1.

1 12. A method of treating diabetic retinopathy or other small vessel disorders
2 associated with diabetes melitis, comprising administering a pharmaceutical composition
3 according to claim 1.

1 13. A method of treating symptomatic dermatographism or dermatitis,
2 comprising administering a pharmaceutical composition according to claim 1.

1 14. A method of treating allergic rhinitis, comprising administering a
2 pharmaceutical composition according to claim 1.

1 15. A method of treating histamine-induced disorders, comprising
2 administering a pharmaceutical composition according to claim 1.

1 16. An anhydrous pharmaceutical composition for the treatment of histamine-
2 induced disorders, comprising a therapeutically effective amount of
3 descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, and a
4 pharmaceutically acceptable carrier.

1 17. The anhydrous pharmaceutical composition of claim 16 wherein the
2 therapeutically effective amount of descarboethoxyloratadine is about 0.1 mg to 10 mg.

1 18. The anhydrous pharmaceutical composition of claim 17 wherein the
2 therapeutically effective amount of descarboethoxyloratadine is about 0.1 mg to 5 mg.

1 19. The anhydrous pharmaceutical composition of claim 16 further
2 comprising a therapeutically effective amount of an analgesic.

1 20. The anhydrous pharmaceutical composition of claim 19 wherein the
2 analgesic is selected from the group consisting of acetylsalicylic acid, acetaminophen,
3 ibuprofen, ketoprofen, naproxen or a pharmaceutically acceptable salt thereof.

4 21. The anhydrous pharmaceutical composition of claim 16 further
5 comprising a therapeutically effective amount of a decongestant.

1 22. The anhydrous pharmaceutical composition of claim 16 wherein the
2 composition is present in one of tablet or capsule form.

1 23. The anhydrous pharmaceutical composition of claim 22 wherein the
2 composition is present in tablet form.

1 24. A method of treating cough, cold, cold-like and flu symptoms and the
2 discomfort, headache, pain, fever and general malaise associated therewith, comprising
3 administering an anhydrous pharmaceutical composition according to claim 16.

1 25. A method of treating diabetic retinopathy or other small vessel disorders
2 associated with diabetes mellitus, comprising administering an anhydrous pharmaceutical
3 composition according to claim 16.

1 26. A method of treating symptomatic dermographism or dermatitis,
2 comprising administering an anhydrous pharmaceutical composition according to claim
3 16.

1 27. A method of treating allergic rhinitis, comprising administering an
2 anhydrous pharmaceutical composition according to claim 16.

1 28. A method of treating histamine-induced disorders, comprising
2 administering an anhydrous pharmaceutical composition according to claim 16.

1 29. A non-hygroscopic pharmaceutical composition comprising
2 descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, lactose and one
3 or more pharmaceutically acceptable inert excipients wherein the composition is
4 substantially free of unbound water.

1 30. The non-hygroscopic pharmaceutical composition of claim 29 wherein
2 the one or more pharmaceutically acceptable inert excipients is selected from the group
3 consisting of non-hygroscopic excipients and low-moisture excipients.

4 31. A solid, non-hygroscopic pharmaceutical composition comprising
5 descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, and a
6 pharmaceutically acceptable carrier.

1 32. An uncoated pharmaceutical composition substantially free of reactive
2 excipients comprising descarboethoxyloratadine, or a pharmaceutically acceptable salt
3 thereof, and a pharmaceutically acceptable carrier.

1 33. A chemically stable pharmaceutical composition in blended or granulated
2 dosage form and substantially free of reactive excipients comprising about 1 % to about
3 50% by weight of descarboethoxyloratadine, or a pharmaceutically acceptable salt
4 thereof, and about 99% to about 50% by weight of a pharmaceutically acceptable inert
5 carrier.

1 34. A pharmaceutical composition for the treatment of histamine-induced
2 disorders comprising large particles of descarboethoxyloratadine, or a pharmaceutically
3 acceptable salt thereof, and a pharmaceutically acceptable carrier.

1 35. The pharmaceutical composition of claim 34 wherein the
2 descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, present in the
3 composition has a particle size distribution in which greater than about 40% by weight of
4 the descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, comprises
5 particles having a size of 250 μm or larger.

1 36. A solid pharmaceutical composition for the treatment of histamine-
2 induced disorders comprising a therapeutically effective amount of coated
3 descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, which comprises
4 descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, coated with an
5 inert coating agent, and a pharmaceutically acceptable carrier.

1 37. The solid pharmaceutical composition of claim 36 wherein the coated
2 descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof, further comprises
3 a granulated formulation of descarboethoxyloratadine, or a pharmaceutically acceptable
4 salt thereof, and a pharmaceutically acceptable inert excipient, wherein the granulated
5 formulation is coated with an inert coating agent.

6 38. The solid pharmaceutical composition of claim 36 or 37 wherein the inert
7 coating agent comprises an inert film-forming agent in a solvent.

1 39. The solid pharmaceutical composition of claim 38 wherein the inert film-
2 forming agent is selected from the group consisting of methylcellulose, hydroxymethyl
3 cellulose, carboxymethylcellulose, hydroxypropylmethylcellulose, hydroxypropyl
4 cellulose, hydroxyethylcellulose, methylhydroxyethylcellulose and sodium
5 carboxymethylcellulose.

1 40. An instant release solid pharmaceutical dosage form for treating
2 histamine-induced disorders, comprising an open matrix network carrying a
3 therapeutically effective amount of descarboethoxyloratadine, or a pharmaceutically
4 acceptable salt thereof, wherein the open matrix network comprises a pharmaceutically
5 acceptable water-soluble or water-dispersible carrier that does not interact with the
6 descarboethoxyloratadine, or a pharmaceutically acceptable salt thereof.